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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,178	12/01/2003	Stephen William Watson Michnick	ODDY 007	8945

7590

10/20/2004

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EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,178

Applicant(s)

WATSON MICHNICK ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-17 is/are rejected.
- 7) ☒ Claim(s) 8 and 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: The species are complementary fragments selected from the group consisting of SEQ ID NOS: 20-1067.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7 and 10-17 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Isaac Angres on 26 August 2004 a provisional election was made with traverse to prosecute the invention of SEQ ID NOS: 583 and 609, related as polynucleotide and encoded polypeptide, to which claims 8 and 9 are drawn. Affirmation of this election must be made by applicant in replying to this Office action.

Specification

3. The disclosure is objected to because of the following informalities: The abstract is too long.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to phosphorescent protein fragments that serve to produce a reporter when reconstituted. The specification does not describe phosphorescent proteins.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

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8. Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In *re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In *re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

9. Claims 1-5, 10, 11, 13, 14, and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, 12, and 13 of copending Application No. 10/856620. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are drawn to species of the instant claims with respect to use of test agents, live cells, measurements, and multiwell format and with respect to the generic reporter molecule in copending claim 5 the copending application describes optical signal generating reporters in copending claims 6 and 12.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

11. Claims 1-5, 10, 11, 13, 14, and 16 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by copending Application No. 10/856620, which has a different inventive entity than the instant application.

12. Claims 1-7 and 10-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/772021. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims species of the instant claimed methods and compositions. With respect to screening putative drugs, the copending methods are species of the instant claimed methods. With respect to optically detectable reporters, the copending claims such reporters in at least claims 6 and 35. With respect to mutant fluorescent proteins, the copending application discloses mutant fluorescent proteins in Table 1 on page 41.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1, 2, 3, 5-7 and 10-17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As discussed above, the instant claims are anticipated

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by copending Application No. 10/772021, which has a different inventive entity than the instant application.

14. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. Claims 2, 6, 7, 15, and 17 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 74-76, 81, and 83 of copending Application No. 10/353090. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

16. Claims 1, 2, 5-7 and 10-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 74-83 of copending Application No. 10/353090. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are either species of the instant claims or have an identical scope as instant claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1, 2, 5-7 and 10-17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As discussed above, the instant claims are anticipated by copending Application No. 10/353090, which has a different inventive entity than the instant application.

18. Claims 1, 2, 5-7 and 10-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 59-75, and 78-80 of copending Application No. 10/154758. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application claims are generic with respect to the instant claims and the copending application discloses green fluorescent protein reporter molecules and mutant green fluorescent protein reporter molecules on page 38.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1, 2, 5-7 and 10-17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As discussed above, the copending claims are generic to the instant claims and copending Application No. 10/154758 discloses green fluorescent protein reporter molecules and mutant green fluorescent protein reporter molecules on page 38.

20. Claims 1, 2, 5, and 10-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 18, and 20 of copending Application No. 09/603885. Some of the claims of the copending application are generic to the instant claims with respect to the reporter molecule, and are species of the instant

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claims with respect to the panel of molecules screened. The copending application discloses fluorescent protein reporter molecules in claim 18.

This is a provisional obviousness-type double patenting rejection.

21. Claims 1, 2, 5, and 10-17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As discussed above, the claims of copending Application No. 09/603885 are generic to the instant claims with respect to the reporter molecule, and are species of the instant claims with respect to the panel of molecules screened. The copending application discloses fluorescent protein reporter molecules in claim 18.

22. Claims 1-7, and 10-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, and 15-18 of U.S. Patent No. 6,428,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because some claims of the issued patent are generic with respect to the reporter molecule and a fluorescent, phosphorescent, or luminescent protein reporter molecule is claimed in claim 13, and discloses a mutant fluorescent protein in column 24. Some of the claims in the issued patent are claims are species of the assayed molecules of the instant claims.

23. Claims 1, 2, 3, and 5-7, and 10-17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As discussed above, some claims of U.S. Patent No. 6,428,951 are generic with respect to the reporter molecule and a fluorescent, phosphorescent, or luminescent protein reporter molecule is claimed in claim 13, and the patent discloses a mutant fluorescent protein in column 24. Some of the claims in the patent are claims are species of the assayed molecules of the instant claims.

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24. Claims 1-7, and 10-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 10, 23, and 25-64 of U.S. Patent No. 6,294,330. Although the conflicting claims are not identical, they are not patentably distinct from each other because some claims of U.S. Patent No. 6,294,330 are to a method that is generic with respect to the reporter molecule and the patent claims a fluorescent, phosphorescent, or luminescent protein reporter molecule in claim 10, and disclosed mutant fluorescent protein reporter molecules in column 29. Some claims of U.S. Patent No. 6,294,330 are drawn to species of assayed molecules.

25. Claims 1-7, and 10-17 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As discussed above, some claims of U.S. Patent No. 6,294,330 are to a method that is generic with respect to the reporter molecule and the patent claims a fluorescent, phosphorescent, or luminescent protein reporter molecule in claim 10, and disclosed mutant fluorescent protein reporter molecules in column 29. Some claims of U.S. Patent No. 6,294,330 are drawn to species of assayed molecules.

26. Claims 1-7, and 10-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33 and 40 of U.S. Patent No. 6,270,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the claimed methods are minor, and the instant compositions are used in the methods of the issued patent. The issued patent discloses mutant fluorescent proteins in column 24.

27. Claims 1, 2, 5-7, and 10-17 rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The differences between the instant claimed methods and the

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methods of claims 33 and 40 of U.S. Patent No. 6,270,964 are minor, and the instant compositions are used in the methods of the issued patent. The issued patent discloses mutant fluorescent proteins in column 24.

Allowable Subject Matter

28. Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

29. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

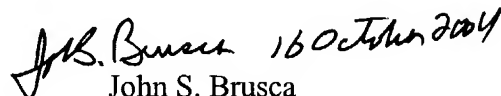
For all other customer support, please call the USPTO Call Center at (800) 786-9199.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John S. Brusca
Primary Examiner
Art Unit 1631

jsb